

Attorney Docket No.: **13257-00040 (UMD-0096)**
Inventors: **Ron et al.**
Serial No.: **09/830,176**
Filing Date: **April 23, 2001**
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REMARKS

Claims 1-19 are pending in this application. Claims 4-6 and 9-19 have been withdrawn from consideration. Claims 1-3, 7 and 8 have been rejected. Claims 1-2 and 7 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Election/Restriction

The restriction requirement placing the claims into Groups I to IV has been deemed proper and made final. Claims 4-6 and 9-19 are withdrawn from further consideration. Accordingly, Applicants are canceling claims 4-6 and 9-19 without prejudice, reserving the right to file continuing applications for the canceled subject matter.

II. Objection to the Specification

The Disclosure has been objected to for lacking an abstract. An abstract has been provided and withdrawal of this objection is respectfully requested.

While the Examiner acknowledges receipt of the Sequence Listing, the specification has been objected because sequences in the specification have not been identified with specific SEQ ID NO sequence identifiers. Applicants have made the appropriate correction to the specification and respectfully request that this rejection be withdrawn.

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III. Priority

Priority to PCT/US99/25477, filed October 29, 1999 and provisional application 60/106,533, filed October 31, 1998 has been acknowledged; however, it is suggested that in order to receive the benefit of the earlier filing date under 35 U.S.C. 119, the instant specification must contain specific reference to the prior applications in the first sentence of the specification. Accordingly, Applicants have amended the specification to incorporate reference to the priority documents.

IV. Claim rejections under 35 USC §102

Claims 1-3, 7 and 8 have been rejected under 35 U.S.C. 102(b) as being anticipated by Freas-Lutz et al. ((1994) *Exp. Hematol.* 22:857-65). It is suggested that Freas-Lutz et al. teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase in a myeloid cell. It is suggested that because the murine leukemia cell line M1 used by Freas-Lutz et al. can be differentiated into various cells of the myeloid lineage upon addition of the appropriate factors in the medium, and the instant specification does not specifically define what a myeloid committed stem cell is, that given the broadest interpretation of being any cell with restricted ability to become a differentiated cell of the myeloid lineage, the M1 cell line meets this interpretation. It is further suggested that Freas-Lutz et al. teach various retroviral constructs using various promoters to analyze expression and activity of glucocerebrosidase and include the use of

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phosphoglycerate gene promoter which is expressed in macrophages, a differentiated myeloid cell.

Applicants respectfully disagree with the Examiner's interpretation of myeloid committed stem cell population disclosed in the instant specification. Applicants have appreciated that spleen-derived myeloid-committed stem cells can advantageously be targeted to express an exogenous nucleic acid and can contribute to the replenishment of the mature myeloid population for at least 9 months. See pages 27-28. This is distinct from the teachings of Freas-Lutz et al., wherein a murine leukemia cell line M1, a bone marrow-derived cell line isolated from a SJ mouse with spontaneous myeloid leukemia, was transduced with retroviral vectors and exhibited high levels of transgene expression. In an effort to clarify the distinctive cells of the instant invention, Applicants have amended claims 1, 2 and 7 to indicate that the myeloid-committed stem cells are spleen-derived. Because Freas-Lutz et al. fail to teach or suggest this essential feature of a myeloid-committed stem cell, Freas-Lutz et al. fail to anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

Claims 1, 2 and 7 have been rejected under 35 U.S.C. 102(b) as being anticipated by Migita et al. ((1995) *Proc. Natl. Acad. Sci. USA* 92:12075-12079). It is suggested that Migita et al. teach the use of retroviral vectors for the transfection and expression of an exogenous nucleic acid sequence encoding glucocerebrosidase, wherein one of the cell types used was a human CD34+ cell which

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represents a population of cells having the capacity to differentiate into various cells of the myeloid lineage.

As indicated *supra*, the cells of the instant invention are derived from the spleen. Migita et al. teach a CD34+ human hematopoietic progenitor cells isolated from bone marrow. See page 12076, column 1 under heading "Tranduction of Target Cells." Accordingly, because Migita et al. fail to teach or suggest the isolation of a myeloid-committed stem cell from spleen, Migita et al. fail to anticipate the instant invention. It is therefore respectfully requested that this rejection be withdrawn.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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